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Sophie Bignon

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PATTON BOGGS LLP
8484 WESTPARK DRIVE
SUITE 900
MCLEAN, VA 22102

EXAMINER

WOODWARD, CHERIE MICHELLE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/580,035	Applicant(s) BIGNON ET AL.	
	Examiner CHERIE M. WOODWARD	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/6/2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5,7-10 and 12-42 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,8,16 and 27-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3,5,7,9,10,12-15,17-26 and 35-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/1/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Formal Matters

1. Applicant's Response and amendments filed 10/6/2010 are acknowledged and entered. Claims 4, 6, and 11 have been cancelled by Applicant. Claims 1-3, 5, 7-10, and 12-42 are pending. Claims 1, 2, 8, 16, and 27-34 are withdrawn as being drawn to non-elected inventions. Claims 3, 5, 7, 9, 10, 12-15, 17-26, and 35-42 are under examination as they are drawn to the species of Formula I.

Response to Arguments

Objections/Rejections Withdrawn

2. Rejections drawn to cancelled claims 4 and 6 are moot in light of the cancellation of the claim. However, to the extent that the subject matter of cancelled claims 4 and 6 have been incorporated into claim 3, rejections over claims 4 and 6 may be reiterated against claim 3.

3. The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, regarding the use of broad and narrow terms in the same claim, is withdrawn.

4. The provisional rejection of claims 3, 5, 7, 9, 10, 12-15, 17, and 21-26 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7, 9-15, and 21-26 of copending Application No. 10/580023, is withdrawn in light of the Terminal Disclaimer filed 10/6/2010.

5. The provisional rejection of claims 3, 5, 7, 9, 10, 12-15, 17, 21, 22, and 24-26 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-7, 9-15, and 21-26 of copending Application No. 10/580037, is withdrawn in light of the Terminal Disclaimer filed 10/6/2010.

6. The rejection of claims 3, 5, 7, 9, 10, 12-15, 17-26, and 35-42 under 35 U.S.C. 112, first paragraph, scope of enablement, is withdrawn in light of Applicant's amendments.

7. The rejection of claims 3, 5, 7, 9, 10, 12-15, 17-26, and 35-42 are rejected under 35 U.S.C. 112, first paragraph, written description, is withdrawn in light of Applicant's amendments.

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Objections/Rejections Maintained

8. The objection over claims 3, 5, 7, 9, 10, 12-15, 17-26, and 35-42 because of the following informalities are maintained. As stated of record, Applicant uses the acronym "PO" to represent "polymers" and "HG" to represent hydrophobic groups in the claims. The uses of these shorthand acronyms are unnecessary and confusing. Applicant is required to use the full word or phrase for each instance of acronyms used in the claims to avoid confusion. Additionally, any parenthetical used in the claims should be deleted and the full terminology used. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 3, 5, 7, 9, 10, 12-15, 17-26, and 35-42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Huille et al., WO 00/30618 (published 2 June 2000) (cited on Applicant's IDS of 9/21/2006) (the English language translation of which is US Patent 6,630,171) (see Patent family history

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for WO 00/30618, last accessed 11/28/2008), Lambert et al., US Patent 7,030,155 (benefit to 5 June 1998), and Singh et al., US Patent 5,102,872 (7 April 1992), as evidenced by the Handbook of Chemistry and Physics, 88~ Ed., 2008 (Viscosities of Liquids, Section 6, pages 175-179) and Akiyoshi, et al., (J Controlled Release. 1998;54:313-320), for the reasons of record and the reasons set forth herein.

Applicant argues that Huille does not teach the critical concentration of polymer greater or equal to 0.9 C1 (Remarks, p. 4). Applicant argues that the IG test has been developed for use with BSA, but that BSA is not part of the claimed composition itself (Remarks, p. 4). Applicant argues that Singh and Lambert do not remedy the deficiencies of Huille (Remarks, p. 4). Applicant argues that Lambert does not disclose how to perform a test in order to determine the 0.9 C1 critical concentration (Remarks, p. 5).

Applicant's significant claim amendments are noted. However, Applicant's amendments and arguments are not persuasive to overcome the prior art of record.

As stated of record, Huille teaches that the concentration of the polymers between 15 and 50 mg/ml are taught at column 5, lines 58-61) (compare instant claim 19, which is dependent on claims 7 and 3). Applicant's argument drawn to the concentration of the polymer being greater than or equal to a minimum gel-inducing concentration "C1" is not persuasive. Huille teaches polymer concentrations within the instantly claimed range of a dependent claim.

Applicant was apprised in the Office Action of 12/3/2008 that, with regard to the gel-forming properties of the claimed composition (claims 3, 4, 35, and 36), the rheological properties of gel formation are inherent physical properties of the composition. For example, compositions comprising polymers carrying hydrophobic groups will spontaneously disassociate proteins from the polymer complex in the presence of bovine serum albumin, as evidenced by Akiyoshi, et al., (J Controlled Release. 1998;54(313-320) (especially at p. 318, column 2, last paragraph to p. 319, column 1, first paragraph, and p. 319, column 2, last paragraph). Absent evidence to the contrary, the bovine serum albumin solution taught in Example 7 would permit the same spontaneous disassociation reaction of releasing the active principle (an interleukin) from the aqueous colloidal suspension on a concentration-dependent basis. Applicant was advised that because the Patent Office does not have the facilities to determine whether the composition taught by the '618 publication forms a gelled deposit in vitro in an aqueous solution of bovine serum albumin at a concentration of 30mg/ml, the burden is on the application to show a novel and unobvious difference between the claimed polymer-containing composition and that of the prior art. See *In re Brown*, 59 CCPA 1036, 459 F.2d. 531, 173 USPQ 685 (CCPA 1972) (holding at 1041, "[a]s a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith")

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and *Ex parte Gray*, 10 USPQ 2d 1922, 1924-25 (PTO Bd. Pat. App. & Int.). Applicant was also advised that the claims are drawn to a composition of matter, the functional descriptions of the structures recited in the claims are inherent to the structure of the composition. Applicant is reminded that a compound and all of its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)).

Additionally, Applicant is reminded that “[w]hen the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicant has not provided any evidence of record to contradict or otherwise clarify or render moot the examiner's inherency arguments. Additionally, the C1 of 0.9 is a lower limit and any polymer concentration above this minimum gel-inducing concentration would inherently meet the limitations of the claims. Further, because instant dependent claim 19 must fall within the rubric of independent claim 3, the innate physical properties of the concentration of polymers in claim 19 (which are met by Huille) would inherently meet the limitations of C1 in the instant claims, as amended.

Applicant is also reminded that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233,235 (CCPA 1955). Applicant has not provided any evidence directed to the criticality of a minimal level of polymer concentration in the claimed compositions.

Applicant's arguments drawn to BSA are moot in light of the cancellation of those limitations in the claims.

Applicant's arguments directed to arguing against the references individually are not productive in advancing prosecution. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Accordingly, the claims remain rejected.

Non-Statutory Double Patenting Rejection

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the

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conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 3, 5, 7, 9, 10, 12-15, 18-22, 24, and 36-40 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-35 of U. S. Patent No. 6,630,171 (7 October 2003), the Handbook of Chemistry and Physics (Viscosities of Liquids, Section 6, pages 175-179) and Akiyoshi, et al., (J Controlled Release. 1998;54(313-320), and Singh et al., US Patent 5,102,872 (7 April 1992) (previously cited of record), for the reasons of record and the reason set forth herein.

Applicant incorporates arguments from the rejection under 35 USC 103(a). Applicant's arguments have been considered, but they are not persuasive for the reasons set forth of record and above. The rejection is maintained.

New Objections/Rejections—Necessitated by Amendment

Claim Objections

14. Claims 3 objected to because of the following informalities: the recitation of “the interleukin(s)” in lines 4 and 5 of claim 3 on page 5 of the amended claims filed 10/6/2010 is grammatically incorrect because no interleukin(s) have previously been referred to in the claim. The recitation of interleukins in the preamble is not sufficient to correspond with “the” interleukins in the body of the claim. In order to overcome this rejection, Applicant should amend the word “the” to the word “an.” Appropriate correction is required.

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Claim Rejections - 35 USC § 112, Second Paragraph

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 41 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 41 contains a broad recitation of a peptide and a more narrow limitation of a glycoprotein. Glycoproteins are peptides. The broad recitation of peptides and the narrower recitation of glycoproteins renders the metes and bounds of the claim unclear and indefinite. Similarly, claim 42 recites cytokines and interferons in the same claim. Interferons are cytokines. Applicant is once again referred to Ex Parte Miyazaki (BPAI 11/19/2008), especially at Slip Op. 11-12.

17. Claim 24 recites the limitation "at least one active principle(s)" in lines 2 and 3. There is insufficient antecedent basis for this limitation in the claim. Claim 24 is dependent on claim 3, which has been amended to delete the phrase "at least one active principle(s)."

Conclusion

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/
Primary Examiner, Art Unit 1647